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GOOD:
Welcome to Immunization Update 2002. We're coming to you live from the Centers for Disease Control and Prevention in Atlanta, Georgia. I'm Cynthia Good and I'll be your host for this live satellite broadcast. This is the eighth annual presentation of Immunization Update. We are pleased that you are spending time with us today to learn about the many new immunization recommendations hat have been made in the past year.

We have two instructors for this part of today's program. Dr. Raymond Strikas is a Medical Epidemiologist in the National Immunization Program at CDC. He has been with the National Immunization Program since 1989.

Our second instructor is Dr. William Atkinson. Dr. Atkinson is a Medical Epidemiologist in the National Immunization Program at CDC. He has also been with the National Immunization Program since 1989.

There have been a lot of developments in immunization in the past year. We've put together today's program to tell you about these changes, and how they will affect your practice. We will begin with a discussion of the recently revised General Recommendations on Immunization. Next, we will talk about recommendations for the use of influenza vaccine, and the new recommendation for the vaccination of healthy children. In our vaccine safety segment we will talk about recent Institute of Medicine reports on hepatitis B and autoimmune disease, and the effect of multiple vaccinations on the immune system. Following vaccine safety, we will present information on immunization registries, and how a registry can benefit your practice. Our vaccine briefs segment will include hepatitis B vaccine, pneumococcal conjugate vaccine, the current vaccine supply situation, a recently licensed DTAP vaccine, and an update on global polio eradication.

Let's look at the objectives for today's session. After this program, we hope you will be able to do these things and much more: Describe two recent immunization recommendations made by the Advisory Committee on Immunization Practices, and describe two recent vaccine safety issues.

Our program will begin with a discussion of new General Recommendations on Immunization right after this pause.

GENERAL RECOMMENDATIONS ON IMMUNIZATION

STRIKAS:
Our first topic today is the recent revision of the General Recommendations on Immunization. This important ACIP statement was published in Morbidity and Mortality Weekly Report in February 2002. Most ACIP statements address a single vaccine or vaccination issue. The General Recommendations on Immunization is

unique among ACIP statements because it provides guidance on vaccination issues common to more than one vaccine. The document is revised on an ad hoc basis, generally every 3 to 5 years. It was first published in November 1976, and has been revised four times since then.

The 2002 revision is the most comprehensive version ever produced. It was also the first ACIP statement published using the new MMWR format, and the first to have a picture on the cover. The picture is Edward Jenner administering the first documented dose of smallpox vaccine in 1796.

New or significantly revised material in the 2002 General Recommendations includes an expanded discussion of contraindications and precautions; methods for alleviation of discomfort caused by injection; prevention of adverse events; and a section discussing vaccination of people with latex allergy. There are also sections discussing vaccination of internationally adopted children and stem cell transplant recipients, discussions of immunization registries and benefit and risk communication and much more.

There are also several recommendations that represent significant changes from earlier versions of the document. We would like to spend some time today discussing some of these changes. These are the timing and spacing of vaccine doses, in particular when doses are given too close together; the nonsimultaneous administration of live virus vaccines; vaccines given by an incorrect route or site; waiting periods after vaccination; and aspiration before administration of vaccine.

The spacing of vaccine doses has been included in the General Recommendations on Immunization since the first edition in 1976. The 2002 edition contains an extensive discussion of the appropriate ages and interval between doses. Arguably, the centerpiece of the document is Table 1. This table contains a listing of every dose of every commonly used vaccine. For each of these doses, the table includes the recommended age for that dose, the minimum age for that dose, the recommended interval to the next dose, and the minimum interval to the next dose. This single table provides all the information you need for scheduling vaccine doses.

ACIP recommends that providers schedule vaccines as close to the recommended age and intervals as possible. The recommended schedule, age for specific doses, and spacing of doses is supported by data from clinical trials of the vaccine.

There are times when it's necessary to give vaccines earlier or closer together than recommended in the routine schedule. Minimum ages and intervals can be used in these circumstances, for instance when a person is behind on the schedule, and it's necessary to catch them up. Minimum ages and intervals could also be used in other situations when the vaccination schedule may need to be accelerated, such as when international travel is impending.

While there are less scientific data supporting the use of minimum intervals and ages, ACIP believes that the response to doses given at these minimum ages and intervals will be acceptable. In practice, vaccine doses are sometimes administered earlier than the minimum age or minimum interval. In the past, ACIP has recommended that doses of vaccine separated by less than the recommended minimum interval- even one day less- should not be considered part of a primary series. ACIP continues to recommend that vaccine doses should not be given at

less than the minimum intervals or earlier than the minimum age. But in an effort to increase the flexibility of the complicated childhood immunization schedule, ACIP now recommends that vaccine doses administered up to four days before the minimum interval or age can be counted as valid. This four day period before the minimum age or interval is being referred to as the grace period. ACIP believes that administering a dose a few days earlier than the minimum interval or age is unlikely to have a significant negative effect on the immune response to that dose. This four day grace period can be applied to all ages and intervals listed in Table 1.

The grace period should NEVER be used when scheduling future vaccination visits. It should be used primarily when reviewing vaccination records, such as for day care or school entry. The 4-day grace period may also be useful in situations where a child visits a provider a few days earlier than a scheduled vaccination appointment. For example, if a child comes to the office or clinic for an ear check 27 days after his or her second DTaP dose, the provider could administer the third DTaP at that visit rather than having the child return for vaccination the next day.

The 4 day grace period recommendation by ACIP will cause a conflict with some state school entry requirements. For instance, most state school requirements mandate the first dose of MMR to be given on or after the first birthday. As a result, not all states will accept this grace period for some or all vaccine doses. You should determine your state program's position on this before you begin using the grace period. The reason that some states are not accepting the grace period is because to do so would mean changing the wording of the school requirement, which often requires an act of the state legislature. So be sure to check with your state immunization program before adopting the grace period. Bill?

ATKINSON:
Thanks, Ray. The second new issue in the General Recommendations concerns the nonsimultaneous administration of live vaccines. Since 1983, ACIP has recommended that whenever possible, parenteral live virus vaccines not administered on the same day should be administered at least 30 days apart. However, ACIP has never provided guidance on a course of action if two live vaccines were given less than 30 days apart.

The recommendation to separate live virus vaccines by 30 days results from concern that the vaccine given first could interfere with response to the vaccine given second. These concerns were initially based on two 1965 studies that indicated that recent measles vaccination reduced the response to smallpox vaccine.

In 2001, the National Immunization Program conducted a study using the vaccine safety datalink system to investigate risk factors for varicella vaccine failure- children who got chickenpox even though they had been vaccinated. This study found that children who received varicella vaccine less than 30 days after MMR vaccination had a significantly increased risk of breakthrough varicella compared to those who received varicella vaccine before, simultaneous with, or more than 30 days after MMR. This study provides additional evidence that interference can occur between two live vaccines given less than 28 days apart. ACIP now recommends that when two live vaccines are not given on the same day but are separated by less than 28 days, the live vaccine given SECOND should be

repeated, unless serologic testing indicates that a response to the vaccine has occurred. For example, if a dose of MMR were given 2 weeks after a dose of varicella vaccine, the MMR should be repeated. The repeat dose should be spaced at least 4 weeks after the invalid dose. The 4 day grace period should NOT be applied to this interval. An exception to this rule is single antigen measles vaccine followed by yellow fever vaccine. Data are available that show that measles vaccine doesn't interfere with yellow fever vaccine given as little as 7 days later.

The next new issue is doses of vaccine given by a nonstandard route or site. In the 1994 revision of the General Recommendations, ACIP recommended that any vaccination using less than a standard dose or a nonstandard route or site of administration should not be counted, and the person should be revaccinated according to age. This recommendation was intended to discourage inappropriate vaccination practices, such as administration of half doses of vaccine, or inappropriate routes of vaccination, particularly vaccination in the gluteus. But this recommendation also led to repetition of some vaccine doses given by routes other than those recommended by the manufacturer, but whose route of administration probably had no significant effect on immunogenicity. An example of this would be the administration of MMR or varicella vaccine by the intramuscular route rather than the recommended subcutaneous route.

ACIP still discourages variance from the recommended route or site of injection. But now ACIP recommends to accept all doses given by a nonstandard route or site- with two exceptions. The exceptions are rabies and hepatitis B vaccine administered in the gluteus area, and hepatitis B vaccine given by any route except intramuscular. There is evidence that administering rabies in the gluteus, and administering hepatitis B vaccine by any route except intramuscular reduces immunogenicity. So these doses should be repeated. The reason for this new recommendation is that available data do not justify repeating vaccines given by the wrong route or site, except rabies and hepatitis B vaccines.

There is one other possible exception to this recommendation you should be aware of. Although not in the General Recommendations, the CDC Division of Viral Hepatitis recommends that hepatitis A vaccine not given by the intramuscular route be repeated using the correct route.

The section of the document that addresses vaccines administered outside the United States has been greatly expanded, including a detailed discussion of internationally adopted children. In the past, ACIP has recommended that all documented doses be accepted as valid if they were administered according to U.S. age and interval recommendations. This recommendation is still generally applicable. However, there is evidence that among some children adopted from outside the U.S., particularly from China, Russia, and eastern Europe, written immunization records may NOT accurately reflect the child's immunity status. ACIP recommends that the immunization records of these children be scrutinized very carefully. Age-appropriate revaccination is generally recommended if there is any doubt about the validity of the written record. For providers or parents who do not wish to repeat every vaccine dose, serologic testing is an option, particularly for tetanus and diphtheria antitoxin in children whose records indicate 3 or more doses of DTP. Additional details are provided, including information about the availability and interpretation of serologic tests.

Another new issue in the General Recommendations is having a patient or client

wait for a certain time after vaccination. Most providers assume that a waiting period after vaccination is to monitor the person for an allergic reaction. Anaphylactic reactions after vaccination are extremely rare if the person is properly screened before giving the vaccine. But syncopal episodes - fainting- are not uncommon. Syncopal episodes are rare in infants and young children, and are most common in older children and adolescents. Every person who has given vaccines for a few years has seen a 200 pound high school linebacker faint after receiving a shot. Serious injury can result from a syncopal episode, including broken bones, head trauma, and brain injury.

One way to prevent a syncope-related emergency pertains to the patient's posture or position during vaccine administration. Infants and young children are usually held by a parent or sitting during their immunizations. It's a good idea for older children, adolescents and adults to sit during vaccination. Sitting during vaccine administration may either prevent syncope or prevent an injury caused by a fall. Most syncopal episodes occur less than 5 minutes after vaccine administration, and nearly 90% occur within 15 minutes. As a result, ACIP now recommends that you should consider observing vaccinated people for 15 to 20 minutes after vaccination, if possible. This is particularly important if you are vaccinating older children, adolescents and adults.

A final issue has to do with vaccination technique, in particular aspiration. Aspiration refers to gently pulling back on the plunger of a syringe to check for blood before injection of the vaccine.

Previous versions of the General Recommendations have recommended aspiration prior to injection, particularly before intramuscular injection. Although this practice is advocated by some experts, and most nurses are taught to aspirate before injection, there is no evidence that this procedure is necessary. There is no evidence that any person has ever been injured because of the failure to aspirate before injection. As a result, the 2002 General Recommendations does not recommend aspiration before injection. It doesn't specifically say NOT to aspirate either. The issue is being left to the individual giving the injection.

If your procedure includes aspiration and blood appears, the needle should be withdrawn, and a new site selected. ACIP doesn't specify what to do with a syringe that has a little blood mixed in with the vaccine. But we think the needle should NOT be reinserted. As soon as the needle enters the tissue it is contaminated. Avoidance of needle stick injury should be your first priority, so discard the syringe and the vaccine in your sharps container, and start over. The simplest way to avoid seeing a little blood in a syringe, and wasting an expensive dose of vaccine ,is to just not aspirate in the first place.

The revised General Recommendations on Immunization should be on every vaccine provider's reading list. You can download a copy from the MMWR website or order a printed copy from the National Immunization Program website. We will give you that address at the end of the program.

GOOD:
Thanks, Bill. We will be back to talk about influenza vaccine in just a moment.

>> IN THE NEXT YEAR, OVER 30,000 ADULTS WILL DIE OF VACCINE-PREVENTABLE DISEASES. AND IT'S NOT NECESSARY. BY IMMUNIZING ADULTS IN A TIMELY MANNER, WE CAN PREVENT MANY DEATHS, IMPROVE THE QUALITY OF LIFE. AND SAVE THE COUNTRY

$10^BILLION A YEAR. INCREASING ADULT VACCINATION RATES, WHAT WORKS, OFFERS PRIMARY CARE PROVIDERS STRATEGIES THEY CAN USE TO INCREASE VACCINATION RATES AMONG THEIR ADULT PATIENTS. IT'S THE GOAL OF THIS INSTRUCTIONAL PROGRAM TO INCREASE HEALTH PROFESSIONALS' KNOWLEDGE ABOUT EFFECTIVE WAYS TO PROVIDE ADULTS THE VACCINES THEY NEED. THE ULTIMATE GOAL IS TO REDUCE THE NUMBER OF THESE NEEDLESS DEATHS. WHAT WORKS IS AN INTERACTIVE CD-ROM PROGRAM. IT PROVIDES CME, CNE, AND CEU CREDIT BASED ON TWO HOURS OF INSTRUCTION TO THOSE WHO COMPLETE THE COURSE AND EXAM. THE PROGRAM OFFERS LEARNERS THE OPPORTUNITY TO TEST THEIR KNOWLEDGE OF VACCINE USAGE, EXPLORE ABOUT VACCINE-PREVENTABLE DISEASES, ACCESS REFERENCE MATERIALS AND ANSWERS TO FREQUENTLY ASKED QUESTIONS. REVIEW INFORMATION ABOUT WHICH STRATEGIES ARE EFFECTIVE, STRATEGIES SUCH AS STANDING ORDERS, CHART REMINDERS, MAILED OR TELEPHONED REMINDERS, AND PATIENT EDUCATION. TEST THEIR KNOWLEDGE OF HOW TO IMPLEMENT THE STRATEGIES FOR MAXIMUM EFFECT. AND DEVELOP AN ACTION PLAN FOR THEIR PRACTICE. THIS WEALTH OF INFORMATION IS AVAILABLE FREE. TO RECEIVE A COPY OF THE WHATWORKS CD-ROM, E-MAIL YOUR REQUEST TO^- WHATWORKS@ATPM.ORG OR CALL 1-850-789-6737.

GOOD:
The Increasing Adult Vaccination Rates: What Works CD is a joint project of the National Immunization Program and the Association of Teachers of Preventive Medicine. It will help you develop and implement strategies to improve vaccination levels among your adult patients. In addition to requesting the CD by Email, you can also order it using the National Immunization Program online publication ordering system. We will give you the address at the end of the broadcast. The CD is free, compliments of CDC and ATPM. Ray?

INFLUENZA VACCINE

STRIKAS:
Thanks, Cynthia. In this segment of the program we want to discuss this year's influenza vaccine recommendations. As you know, ACIP updates it's influenza vaccine recommendations every year. This year's ACIP statement was published in April 2002. The most significant changes in this year's recommendations are the timing of influenza vaccination by risk group; the 2002- 2003 vaccine virus strains; the availability of certain influenza vaccine doses with reduced thimerosal content, and influenza vaccine for children aged 6 to 23 months of age. We will discuss the first 3 issues briefly, and the new pediatric vaccination recommendation in more detail.

In the United States and other temperate areas of the northern hemisphere, influenza occurs most commonly between December and March. The optimum time to vaccinate is usually during October and November. As you are aware, there have been substantial delays in the distribution of influenza vaccine during the last two years. Influenza vaccine production is complex, and it is possible that delays in distribution could occur again.

To minimize disruptions caused by these delays, ACIP now recommends that providers focus their vaccination efforts in October and earlier on persons at high risk of complications of influenza and their household contacts, and health-care workers. Vaccination of children 6 months to 9 years of age who are receiving vaccine for the first time should also begin in October because they need a second dose 1 month after the first. Vaccination of all other groups should begin in November, including healthy people aged 50 to 64 years, and other people who wish to reduce their risk for influenza infection.

Vaccine should be offered to people at increased risk of complications of influenza when they access medical care in September, if vaccine is available. Vaccination of high risk persons early is easier if offices have a reminder and recall system in place.

Here are the groups at high risk of complications of influenza. First and foremost, all persons 65 years of age or older, and persons 6 months of age and older with any of a variety of chronic illnesses should be vaccinated. Healthy children 6 to 23 months of age are at increased risk of complications of influenza - we will discuss vaccination of this group in more detail in a few minutes.
The chronic illnesses that increase the risk of influenza complications include: pulmonary diseases such as emphysema and asthma; cardiovascular diseases; and metabolic diseases like diabetes. Additionally, renal dysfunction, like chronic renal failure or nephropathy; hemoglobinopathies, like sickle cell disease; and immunosuppression, including HIV, are high risk conditions. In addition to seniors and people with chronic illnesses, other risk groups include residents of long term care facilities, and persons 6 months to 18 years of age receiving chronic aspirin therapy, because of the risk of Reyes. Finally, most pregnant women are recommended to be routinely vaccinated- specifically those who will be in the second or third trimester of pregnancy during influenza season.

Health care workers are at increased risk of exposure to influenza. Also, a health care worker with influenza could expose many of his or her patients who are at high risk of complications of influenza. So health care workers are a high priority for early supplies of influenza vaccine. Yet in 2000, only about 38 percent of health care workers reported having been vaccinated in the previous year. Health care workers- ALL health care workers- owe it to their patients to receive annual influenza vaccine, and to receive it early in the season. Bill?

ATKINSON:
Ray, there seems to be a perception that influenza vaccination is an October activity. It's been difficult to convince providers to continue providing vaccine to their patients into December and beyond. It's critical that we change this perception.

This graph shows the month in which influenza activity peaked in the United States from 1976 through 2001. Influenza activity peaked in December in only 16 percent of seasons. Activity peaked in January in 24 percent of seasons and in February in 40 percent of seasons. The message here is that December is NOT too late to receive influenza vaccine. Vaccination in January or even February can still prevent a lot of influenza.

ACIP recommends that providers should continue to offer influenza vaccine to their patients, especially those at high risk of complications, and to health care workers in December. Providers should continue to vaccinate throughout influenza season as long as vaccine is available, even after influenza activity has been documented in the community.

The influenza vaccines available in the U.S. are inactivated subunit vaccines. The two types of subunit vaccine available contain either split virus, or

purified hemagglutinin. The whole inactivated virus vaccine is no longer available in this country. Available influenza vaccines are trivalent- meaning they contain 3 different viruses, two type A viruses and one type B. The viruses contained in the vaccine are chosen each spring, based on surveillance of current circulating strains. Only the B virus component was changed this year.

The vaccine recommended for the 2002- 2003 season includes A/Moscow/10/99- the H3N2 strain; A/New Caledonia/20/99- the H1N1 strain, and B/Hong Kong/ 330/2001. For the A/Moscow antigen, manufacturers will use the antigenically equivalent A/Panama/2007/99 strain. A different, antigenically equivalent B strain may be substituted for the B/Hong Kong antigen. These substitute viruses will be used because of their growth properties, and because they are representative of influenza viruses likely to circulate in the United States during the 2002- 2003 influenza season.
Influenza vaccine is made from highly purified, egg-grown viruses that have been made noninfectious. Because the vaccine viruses are initially grown in embryonated hens' eggs, the vaccine might contain a small amount of residual egg protein. Consequently, this vaccine should not be used, or used with extreme caution, among persons with anaphylactic egg allergy.

Influenza vaccine distributed in the United States also contains thimerosal, a mercury- containing compound, as the preservative. Thimerosal has been used as a preservative in vaccines since the 1930s. There is no evidence of harm caused by thimerosal in vaccines. But in 1999, the U.S. Public Health Service and other organizations recommended that efforts be made to reduce the thimerosal content in vaccines to decrease total mercury exposure, chiefly among infants and pregnant women. Since mid- 2001, all routinely administered childhood vaccines for the U.S. market have been manufactured either without thimerosal, or with only trace amounts of thimerosal. This has resulted in a substantial reduction in the total mercury exposure from vaccines for children.

For the 2002- 2003 influenza season, a limited number of doses of reduced thimerosal- content influenza vaccine will be available. Currently, reduced thimerosal content vaccine is available from only one manufacturer, Evans Vaccines, marketed with the trade name Fluvirin. Fluvirin contains less than 1 microgram of thimerosal per dose, compared to 25 micrograms per dose for other influenza vaccines. Fluvirin is approved for use in persons 4 years of age and older. It should NOT be used in children 6 months to 4 years of age.

ACIP believes that because of the known risks for severe illness from influenza infection and the benefits of vaccination, the benefit of influenza vaccine with reduced or standard thimerosal content outweighs the theoretical risk, if any, from thimerosal. The removal of thimerosal from other vaccines further reduces the theoretical risk from thimerosal in influenza vaccines.

Another addition to this year's influenza recommendations is a discussion of vaccination of healthy children. Influenza is a common cause of respiratory illness among children. Rates of hospitalization among children less than 24 months of age are as high as rates among seniors.

After much discussion, ACIP is taking the first steps toward what will eventually be the routine annual influenza vaccination of ALL children 6 to 23 months of age.

We asked Dr. Carolyn Bridges, a medical epidemiologist in CDC's Influenza Branch, and Dr. Bonnie Word, chair of ACIP's influenza working group, to talk to us about the impact of influenza in children, and ACIP's new recommendations.

BRIDGES:
Influenza is an acute infectious disease caused by the influenza virus. Epidemics of influenza typically occur during the winter months in the United States and other temperate areas of the northern hemisphere. During these annual winter epidemics in the United States, 10%-20% of the population may be affected. Complications of influenza are mostly respiratory, and include primary influenza pneumonia and secondary bacterial pneumonia, often caused by Streptococcus pneumoniae, or pneumococcus and other bacteria. Influenza can also cause worsening of underlying illnesses, such as congestive heart failure and diabetes.

Infection with influenza virus can be fatal. Influenza-related deaths can result from pneumonia as well as from exacerbations of cardiopulmonary conditions and other chronic diseases. An average of approximately 20 thousand influenza-associated deaths occur each year in the United States, with more than 40 thousand deaths in some years. Persons 65 years of age and older account for more than 90% of these deaths. In the United States, pneumonia and influenza deaths may be increasing in part because the number of older persons is increasing.

Influenza is also a common cause of hospitalization. During the past 30 years, the estimated overall number of influenza- associated hospitalizations in the United States ranged from 16,000 to 220,000 per epidemic with an average of 114,000. While persons 65 years of age and older account for more than 90% of influenza-related DEATHS, this age group accounts for about 43% of influenza-related hospitalizations. Groups traditionally considered at increased risk of complications of influenza include persons 65 years of age and older, and persons of any age with underlying illness, such heart or lung disease, diabetes, renal failure, or immune suppression. Healthy women in the second and third trimesters of pregnancy are also at risk of complications compared to women of the same age who are not pregnant. Studies also indicate that rates of influenza-related hospitalization are higher among young children compared with older children.

The interpretation of increased hospitalization rates among children during the winter has been difficult because of the co-circulation of influenza and respiratory syncytial viruses, or RSV. RSV is also a cause of serious respiratory illness among children during the winter. Recent studies have attempted to separate the effects of RSV and influenza virus. This table summarizes age-specific rates of influenza related hospitalizations per 100 thousand population from several published studies. The rates among people with high risk medical conditions - such as underlying heart or lung disease- are shown in the center column, and those without high risk conditions in the right column. In these studies, children zero to 4 years of age- shown in the first row- had rates of hospitalization higher than any other age group through age 64. The hospitalization rate among children zero to 4 years with high risk medical conditions was 500 per 100 thousand population, 5 times higher than healthy children of the same age. This rate of hospitalization was higher than any other age group with high-risk conditions through age 64. In some studies the hospitalization rate among young children with high-risk medical conditions

was even higher than among people 65 years and older.

The risk of complications and hospitalization is not equal for all children. This table shows rates of influenza related hospitalizations by age of a medicaid population in Tennessee. By far the highest rates of hospitalization were among children 11 months of age and younger, particularly those with high-risk medical conditions, shown in the center column. But rates of hospitalization were also very high through 2 years of age in both healthy children and those with high-risk conditions. Rates of hospitalization in HEALTHY children 2 years of age and younger were higher than rates among older children with high risk underlying medical conditions- groups for which influenza vaccine has been recommended for many years.

This table shows the results of a second study among healthy children enrolled in two health maintenance organizations. In this study, children zero through 23 months of age had rates of hospitalization from influenza of 144 to 187 per 100 thousand children. This rate was more than 5 times higher than for healthy children 2 to 4 years of age, and 5 to 17 years of age.
There are several reasons why young children are at increased risk of hospitalization from influenza. The most important is probably because infection with influenza virus at this age represents the first experience with the virus. After the first infection with influenza virus, the child develops immunologic memory to influenza viruses, and subsequent infections with similar viruses produce less severe illness.

For several years, the Advisory Committee on Immunization Practices and the American Academy of Pediatrics have been discussing options to reduce the burden of influenza among young children. Routine annual vaccination of children 6 months and older with high risk medical conditions has been recommended for many years. For the 2002- 2003 influenza season ACIP and AAP have taken the first steps toward the prevention of influenza in ALL children 6 months to 23 months of age.

What is the Advisory Committee on Immunization Practices' recommendation on influenza vaccination of children?

DR. BONNIE WORD:
ACIP has always recognized that were certain children who have high risk medical conditions, who require yearly influenza vaccination. However, more recently ACIP has become aware that there's another group of children - and these would be healthy children those children less than 2 years of age who have increased rates of complications as well as increased rates of hospitalization when infected with influenza. As a result, ACIP is now recommending that all children less than 23 months of age or should I say between 6 months and 23 months of age receive influenza vaccine when feasible. So the wording specifically is that for practitioners it is encouraged to administer vaccine to those children between 6 months and 23 months of age when feasible.

What are the obstacles to a recommendation for influenza vaccination all children 6 - 23 months of age?

ACIP anticipates making a full recommendation for administration of influenza vaccine to all children between 6 and 23 months of age within the next three years. However, prior to making this recommendation there are several obstacles

that must be overcome. First and foremost is education. Education of not only the health care providers but also the parents. Many individuals on both sides feel that influenza is a viral illness - it's simply a right of passage. I think once they recognize that there are increased hospitalization rates and complications associated with influenza, particularly in younger children, I think they will begin to look at this from a different perspective. The other thing is that we do have a vaccine that is available - a vaccine that can help prevent and diminish the complications associated with it and I think once that message gets out people are going to be more willing to utilize it. The next thing is just looking at the feasibility and the logistics of administering this vaccine in a certain time period. Unlike most vaccines that practitioners are accustomed to administering, this one will be administered on a seasonable basis. There is a certain time frame- a time window where's it's optimal for children to receive it - or should I say all individuals to receive vaccination. That will be something different and something that they'll have to adjust and get accustomed to within their own practices and find out what's the best way for this to work within their specific practices. The third thing will be reimbursement issues. You can't ask a group of practitioners to begin to administer vaccine and not have found ways where they will be adequately reimbursed for their time as well as the administration costs that they will incur.

What other strategies can help prevent influenza in young children?

We spend a great deal of time focusing on children 6 to 23 months of age. However, the group of children who are actually most vulnerable for influenza, its complications and hospitalizations will be those infants less than 6 months of age. Unfortunately, there is no vaccine available. So the only way we can target those infants and try to prevent infections and complications would be to target their contacts. And this would include all their household contacts, not just their parents, but all their household contacts. As well as administering vaccine to all individuals who have prolonged contact with these children. For example, it may the individual who is providing daycare services. They may be spending 4 to 6 hours a day with that child. That would l be an individual who you would want to immunize.

ATKINSON:
The new ACIP recommendation to encourage influenza vaccination of all children 6 to 23 months of age, when feasible, is only the first step. As Dr. Word mentioned, we expect ACIP and the Academies of Pediatrics and Family Physicians to recommend ROUTINE annual vaccination within the next 3 years. If you provide health care services to children, you should begin thinking about how to integrate annual influenza vaccination into your practice. At the very least, you should be vaccinating children 6 months and older who have underlying medical conditions. This will help acclimate your office to a seasonal vaccine, and get ready for the day when influenza vaccine becomes a part of routine childhood vaccination.

For the 2002-2003 influenza season there will be no changes to groups of children eligible for influenza vaccine under the Vaccines for Children- or VFC- program. Coverage currently includes children 6 months of age and older with high risk medical conditions. But NEXT year- the 2003-2004 influenza season, VFC coverage for influenza vaccine will be extended to healthy children aged 6 to 23 months of age, and children aged 2 to 18 years who are household contacts of

children 2 years of age and younger.

As you know, influenza vaccine distribution was delayed during the last 2 influenza seasons. Based on manufacturer's estimates, projected influenza vaccine production for 2002- 2003 is between 92 and 97 million doses. This is an increase of 5 to 10 million doses compared to last year. We hope you have already ordered your influenza vaccine for the 2002-2003 season. If you haven't, influenza vaccine is still available for purchase, and you should place your order as soon as possible. Both Aventis Pasteur and Wyeth have informed us that all of their influenza vaccine for the 2002-2003 season has been pre-booked, but their waiting lists remain open. Evans vaccine is still available from several distributors. Details of influenza vaccine supply and availability, and contact information for manufacturers and distributors is available on the National Immunization Program website. We will give you the address at the end of the program. While you are visiting the website, have a look at our new educational and promotional information for influenza vaccine. For this season there are new flyers describing the timing of influenza vaccination, and myths concerning influenza vaccine. You can download the flyers for your office. They are free.

GOOD:
Thanks, Bill. We will be back to talk about two Institute of Medicine reports on vaccine safety in just a moment.
[VIDEO PROMO FOR IMMUNIZATION ACTION COALITION]

VACCINE SAFETY

GOOD:
Welcome back to Immunization Update 2002. Joining us for this part of the program is Donna Weaver. Donna is a nurse educator in the National Immunization Program at CDC. Ms. Weaver has a masters degree in nursing, and has been working in immunization programs since 1996.

In this segment of today's program we would like to discuss two recent vaccine safety reports by the Immunization Safety Review Committee of the Institute of Medicine. Before we talk about the specific reports, it's useful for you to know a little background on the Institute of Medicine and their vaccine safety activities.

The Institute of Medicine, or IOM, is part of the National Academy of Sciences, a private, nonprofit society of scientists and researchers. The National Academy of Sciences was granted a charter by Congress in 1863, and was mandated to advise the federal government on scientific and technical matters. The Institute of Medicine was established by the National Academy of Sciences in 1970 to advise the federal government on issues related to the health of the public. IOM also acts independently to identify important issues of medical care, research and education.

The IOM has a long history of involvement in vaccine safety. It issued 4 major reports on this subject between 1977 and 1994, and has conducted several smaller studies and workshops focused on various vaccine safety topics.

In 2000, CDC and the National Institutes of Health requested that IOM establish an independent expert committee to review the available evidence on a series of immunization safety concerns. The Immunization Safety Review Committee is made

up of 15 members with expertise in a variety of medical fields, nursing, epidemiology, biostatistics and ethics.

Because of the sensitive nature of this subject, IOM established strict criteria for committee membership to minimize concerns about conflict of interest. These criteria prevented participation by anyone with financial ties to vaccine manufacturers or their parent companies, previous service on major vaccine advisory committees, or prior expert testimony or publications on issues of vaccine safety.

The first Immunization Safety Review Committee report- which addressed measles mumps rubella vaccine and autism- was released in April 2001. The second report on thimerosal containing vaccines and neurodevelopmental disorders was released in October 2001. In February, 2002, the committee released its third report which addressed multiple immunizations and immune dysfunction, and released its fourth report in May, 2002, on hepatitis B vaccine and demyelinating disorders.

For each hypothesis that is examined, the committee assesses both the scientific evidence and the issue's significance to society. For these reviews, the scientific assessment has two parts: an examination of evidence that the hypothesis is biologically plausible; and an examination of the evidence for a causal relationship between the vaccine and the adverse event.

In looking at the significance to society, the committee includes a review of health risks associated with the vaccine preventable disease and with the adverse event in question and other societal concerns. The findings of the scientific and significance assessments provide the basis for the committee's recommendations. The Immunization Safety Review Committee uses a framework for assessing causality used for reviews of vaccine safety in 1991 and 1994.

The categories of causal conclusions are: no evidence; evidence is inadequate to accept or reject a causal relationship; evidence favors rejection of a causal relationship; evidence favors acceptance of a causal relationship; and evidence establishes a causal relationship. The most definitive category is "establishes causality", which is reserved for those relationships where the causal link is unequivocal. An example of this is the association of oral polio vaccine and vaccine associated paralytic polio. "Favors rejection" is the strongest category in the negative direction. Notice that the committee does not include a category of "establishes no causal relationship". This is because it's virtually impossible to prove the ABSENCE of a relationship with the same certainty that is possible in establishing its presence. That is, it's very difficult to prove "NEVER". The "no evidence" category means there is a complete absence of clinical or epidemiological evidence, rather than meaning that no causal relationship has been shown.

Committee assessments begin from a position of neutrality regarding the specific vaccine safety hypothesis under review. That means there is no presumption that a specific vaccine or vaccine component does or does not cause the adverse event in question. The weight of the available evidence determines whether it's possible to move from that neutral position to a finding FOR causality or AWAY FROM causality. This is different than in a typical scientific study in which the hypothesis is that there is NO relation, and evidence must be sufficient to reject that hypothesis.

We will now discuss the two most recent IOM reports, beginning with the February 2002 report on multiple vaccinations and immune system dysfunction. Ray?

STRIKAS:
Thank you Cynthia. Although most people realize the benefits of vaccinations, a recent survey showed that approximately one quarter of parents believe that infants get more vaccines than are good for them, and that too many immunizations could overwhelm an infant's immune system. Because immune system dysfunction is a broad term, the committee focused its review on the following questions: do multiple immunizations have short-term effects on developing infants' immune systems that leave them susceptible to other infections? Does exposure to multiple vaccines directly and permanently redirect the immune system toward autoimmunity, as reflected in type 1 diabetes? And does exposure to multiple vaccines directly and permanently redirect the immune system toward allergy, as reflected in asthma?

In order to conduct their review, the committee focused on defined conditions like diabetes mellitus and asthma for which studies can be reviewed and compared, as opposed to vaguely defined, atypical or non-specific conditions. The main concern about multiple immunizations is whether an infant's immune system is overloaded by all the vaccines on the recommended immunization schedule. This concern has increased as the number of recommended vaccines has increased.

The committee found that the number of antigens in the recommended childhood immunization schedule actually has decreased in the past 30 years, even though the number of vaccines and vaccine doses has increased. This decrease is due to removal of smallpox and whole cell pertussis vaccines from the childhood immunization schedule, which eliminated 200 and 3 thousand antigens, respectively. The committee also reviewed estimates that suggest the capacity of the infant immune system is at least 1000 times greater than what is required to respond to immunizations.

The committee examined the so-called hygiene hypothesis. This hypothesis suggests that because we live in cleaner environments our immune systems are weaker today than they were in the past. The committee's report points out that the potential role of vaccine preventable diseases as part of the hygiene hypothesis is minimal. In fact, the number of infections prevented by immunization is actually quite small compared with the number prevented by other interventions such as clean water, food, and living conditions. The committee concluded that this mechanism is only theoretical and if proven, immunizations would play an insignificant role.

The IOM Immunization Safety Review Committee's most important conclusions were that the available scientific evidence does not support the hypothesis that the infant immune system is inherently incapable of handling the number of antigens that children are exposed to during routine immunizations. There is evidence for the existence of biological mechanisms by which multiple immunizations could possibly influence an individual's risk for infections. But the epidemiologic evidence- that is, data from studies of vaccine exposed populations and their control groups- favors rejection of a causal relationship between multiple immunizations and increased risk for infections or for type 1 diabetes mellitus. Finally, the epidemiologic evidence regarding increased risk for allergic disease, particularly asthma, was inadequate to accept or reject a causal

relationship.

The Committee recommended limited but continued public health attention to this issue in the form of policy analysis and communication strategy development. They recommended and endorsed a number of research activities, including the use of existing vaccine safety monitoring systems to study questions related to asthma and other allergic disorders, as well as diabetes mellitus and other important autoimmune diseases. The Committee did NOT recommend a review by national and federal vaccine related advisory groups of the licensure or schedule of administration of vaccines on the basis of concerns about immune dysfunction.

These recommendations will be considered in depth by Public Health Service agencies during the next several months. Donna?

WEAVER:
Thanks, Ray. As you know, ACIP and other advisory committees recommend hepatitis B vaccination for all infants, adolescents and high risk adults. These recommendations have been viewed with skepticism by some people because of concerns about the safety of the vaccine, and because of a perception that hepatitis B infection is not a serious risk to the general population.

The Immunization Safety Review Committee released a report in May 2002 that addressed the relationship between hepatitis B vaccine and several demyelinating neurological disorders. The disorders included multiple sclerosis, optic neuritis, acute disseminated encephalomyelitis, transverse myelitis, Guillain Barre Syndrome and brachial neuritis. The committee focused on these conditions because they are serious neurological disorders and known clinical entities. In addition, published epidemiological studies and case reports are available that investigated the association of some of these diseases with hepatitis B vaccine, and a substantial amount of literature exists on the pathophysiology of several of these conditions. Most of the epidemiological evidence examined by the committee concerned the connection between hepatitis B vaccination and the diagnosis of MS, or the risk of a relapse in patients previously diagnosed with MS.

Multiple sclerosis is the most common inflammatory demyelinating disease of the central nervous system in humans. Approximately 300,000 people, or about 0.1% of the population, have been diagnosed with the disease in the United States. Women are affected about twice as often as men. The incidence of the disease is highest in persons between 20 and 40years of age, but it has been diagnosed in children as young as 2 years, and in older people. The severity of the disease is variable, and can range from subclinical forms that are diagnosed only after death from other causes to hyperacute forms that lead to death within the first few months after onset. The cause of multiple sclerosis remains elusive, but susceptibility appears to involve both genetic and environmental factors. 2 to 5 percent of fraternal twins and other siblings of persons with MS will be affected. But 30 to 35 percent of monozygotic or identical twins will be affected if the other twin has the disease.

The committee concluded that there is at least a theoretical basis for the hypothesis that vaccines, including hepatitis B vaccine, could cause demyelinating disorders. The details of these immunologic mechanisms are beyond the scope of this program, but basically involve the destruction of nerve tissue

through the development of antibody to myelin following vaccination. Another possible mechanism is the release of inflammatory mediators such as cytokines following vaccination that could participate in the demyelination process. But the biologic evidence for these mechanisms is weak.

From the data reviewed, the Committee concluded that the evidence favors rejection of a causal relationship between hepatitis B vaccine administered to adults and either onset or relapse of multiple sclerosis. There are no epidemiological data regarding the relationship of hepatitis B vaccination in infants and young children and the risk for MS. The Committee could not extend the causality conclusion based on studies in adults to include a possible risk to infants and young children.

The Committee concluded that the evidence is inadequate to accept or reject a causal relationship between hepatitis B vaccine and all other demylenating conditions, such as optic neuritis, transverse myelitis, and Guillain Barre syndrome.

Overall, the committee found little indication that safety concerns are a major barrier to acceptance of hepatitis B vaccination in the United States. This is evident from National Immunization Survey data that showed 90 percent vaccination coverage among children 19 to 35 months of age in 2000. But the committee also concluded that concerns about hepatitis B vaccine remain significant for some parents and workers who are required to take the vaccine because of occupational risk.

The Immunization Safety Review Committee did NOT recommend a policy review of hepatitis B vaccine by any of the national and federal vaccine advisory bodies on the basis of concerns about demyelinating neurological disorders. Among other things, the committee recommended surveillance of multiple sclerosis and other central and peripheral nervous system demyelinating disorders, specifically in health care workers and those born since 1991. They also recommended further public health attention on the issue in the form of additional research and communications to increase understanding of the basis for hepatitis B recommendations in the United States.

Both of these Institute of Medicine reports on vaccine safety are excellent reviews, and we recommend that all vaccination providers familiarize themselves with them. These, as well as the earlier reports on MMR and autism, and thimerosal containing vaccines are available on the National Immunization Program website. We will give you the address at the end of the broadcast. Cynthia?

GOOD:
Thanks Donna. We will be back in just a moment to discuss immunization registries.

>> FROM THE FIRST DAY OF LIFE, OUR CHILDREN DEPEND ON US TO FEED AND CLOTHE, NURTURE AND PROTECT THEM. WE, IN TURN, DEPEND ON THE BEST ADVICE WE CAN FIND. IN RECENT YEARS, CONCERNED PARTS HAVE BEGUN TO RAISE SERIOUS QUESTIONS ABOUT THE BENEFITS AND RISKS OF VACCINES. QUESTIONS THAT DESERVE EQUALLY SERIOUS ANSWERS. >> MARY CATHERINE WAS BORN SOON AFTER A FRIEND OF MINE MENTIONED THAT SHE HAD CONCERNS ABOUT SAFETY AND EFFICACY OF VACCINATIONS. SO WHILE I WAS INVESTIGATING AND TRYING TO FIND OUT IF SHE

WAS RIGHT ABOUT THIS, AND PROBLEMS WITH VACCINES, I DID NOT HAVE MARY CATHERINE VACCINATED. >> AS A PARENT WE ALL WANT SO DESPERATELY TO DO WHAT IS RIGHT, WHAT IS BEST FOR OUR CHILDREN. WITH REGARD TO VACCINES, I THINK THERE'S A LOT OF CONFLICTING INFORMATION OUT THERE. MY HOPE IS BY TALKING TO PARENTS ABOUT VACCINES, MY HOPE IS WHAT THEY ARE, HOW THEY WORK, HOW THEY CAN STILL MAKE AN IMPORTANT DIFFERENCE IN OUR LIVES WE CAN TAKE THE FEAR OUT OF DISCUSSION AND FOCUS INSTEAD ON THE FACTS.

IMMUNIZATION REGISTRIES

GOOD:
The clip you just saw was from a video titled Vaccines: Separating Fact From Fear. The video is 27 minutes long, and was produced by the Vaccine Education Center at the Children's Hospital of Philadelphia. It's intended to address parents most common concerns and misconceptions, such as the need for vaccines, MMR and autism, safety of multiple vaccines, and much more. The tape is an excellent educational resource for your office, and you can get a copy free of charge. It can be ordered from the Vaccine Education Center website at www dot vaccine dot chop dot edu. That's the Children's Hospital of Philadelphia Vaccine Education Center website at www.vaccine.chop.edu. The website also contains other excellent educational material for both parents and providers, so take advantage of it. The Vaccine Education Center is supported entirely by private funds and does not accept funding from either pharmaceutical companies or the government, which might be important to some of your more skeptical parents.

In this segment of the program we would like to discuss immunization registries.

Having a readily accessible, central repository of immunization records helps assure that people get the vaccines they need, when they need them. Registries ultimately save time and money, and reduce inconvenience for everyone.

The need for registries is greater today than ever before. Nationally, 20% of children move by the age of two, and change providers for this or other reasons. This leads to incomplete documentation in a single medical record. As you are well aware, the childhood immunization schedule is complex. A registry can help simplify the process of deciding which vaccine is due at a visit. Parents and patients become complacent about returning for vaccination appointments when disease rates are low. A registry can help generate reminder and recall notices for your patients who miss appointments. Finally, a registry can facilitate the exchange of vaccine information among providers and improve continuity of care.

We asked Dr. Rob Linkins, from the Data Management Division of the National Immunization Program, to tell us more about registries, and how they can benefit your practice.

LINKINS:
Hello, I'm Rob Linkins wth the National Immunization Program's Immunization Registry Support Branch. We work with registries across the country to promote development and implementation of electronic immunization information systems. There's a lot of interest today in immunization registries. They've come a long way from the early explorations around the country to become a widely available practice tool for pediatricians and family physicians.

In simple terms, an immunization registry is a computerized system that

physicians use to submit and retrieve immunization histories from a secure database. Some registries use the internet, some use a network, and others link up by modem. But the way they work and the benefits are similar: A registry can make scheduling, documenting and knowing what immunizations to give easier. Personally, I think registries are great, but what's important is what physicians who are using them have to say. So we headed out to California to visit a couple of practices that use a registry. Our first stop is the LaSalle Clinic in San Bernardino California, right on historic Route 66. LaSalle belongs to the Inland Empire Immunization Tracking System. This registry covers a huge two-county territory of 27,000 square miles with a population of more than 3 million and over 50,000 births a year. LaSalle is a thriving pediatric and family practice with five clinic sites in the two Inland Empire counties. They have been participating in a registry since 1997.

MAN:
I'm Ryan Zane and this is Adam. We have an appointment with Dr. Hernandez. And we got this postcard saying my son needs some shots. We thought he was all caught up. What will be getting today?

CLERK:
OK sign in here and the nurse will call you.

DR. CHERYL EMOTO:
We have a very busy practice here, with three full-time physicians, one PA and six Medical Assistants. We're now averaging about 60 to 70 kids a day. Last year some 20,000 children under age 5 passed though our five clinics in the course of the year. When we were first approached—it was five or six years ago--about the idea of an immunization registry, it was a new concept, very visionary, to share a child's immunization history with other doctors in our community. And now, we have all five of our clinics logging into the Inland Empire registry. A lot of the private physicians in this area are members also. And we're really looking forward to the day when it goes statewide in California. We were a little concerned when we got started about what it might cost us. Actually it turned out there weren't really many costs.

We didn't have a computer at the time, but we were fortunate to have a couple donated. Since then, we've opened three additional clinics which are all operating our registry system. Based on our experience, we could easily justify the investment for purchasing the computers to run the registry at our new sites. The fact that the registry system itself was free made a big difference to us. And the registry provided all the training for our staff, so that was free, too. Our doctors still decide for themselves what immunizations are needed on a visit, but the way the registry forecasts what shots are needed has helped make them sure they're not missing an opportunity. We get a lot more prompting and it's made us more "immunization aware." And, as a result, fewer kids fall through the cracks. We think using the registry here has made a lot of difference. Kids are completing the basic series earlier. Our immunization levels now measure in the 80's, much higher than when we joined the registry. Data entry can be a challenge. Although we all have access to the computers and can do some of the entry ourselves, a lot of the responsibility falls to our medical assistant.

BARBER:
When I started, I loved being one of the early system pioneers. I could give

feedback to the registry developers on data entry to help make the system meet my needs. And it really does. I'd say the system is pretty doctor-office friendly now. Plus, the registry help desk is always there to answer my questions and they are wonderful! We enter patient records every day but we can also be flexible about when data entry is done. A nurse can enter the information right after giving the shots, or it can be done later that day or the next day. I've done a lot of it myself over the past 5 years. Once a child's record is added, updates are really fast. Like now we can print out an updated record for the chart before its re-filed.

I'd say one of the most popular features of the registry is being able to print out a copy of replacement immunization records—our yellow cards—for families. We can print them now in just seconds. It's a great time saver. It saves the parents a big headache, especially if they can't find the record and they need it to get their child into school or day care or even camp. The registry's a huge help when a child moves from one facility to another or from one town to another. Now I know I can just go to the computer and I have the whole record right there.

MAN:
Thanks. I'm sure his child care center will be glad to see this.

EMOTO:
We didn't have any routine reminder system for scheduled immunizations before we started with the registry. Now, the registry sends out reminder postcards based on the next scheduled due date for shots. This has turned out to be a great service and it's helped to reduce our no-shows.

LINKINS:
In case you think LaSalle's experience is somehow unique, we went to San Diego to visit a big urban practice. San Diego is California's second biggest city, with a population of one point two million people. San Diego County overall has a population of nearly three million. Their registry has recently joined forces with neighboring Imperial County to expand across the southern-most end of the state. Between the two counties they report just under 50,000 births a year. The Children's Health Care Medical Associates is a private pediatric practice that has been using the registry for nearly three years. Dr. Allen Schwartz and his wife Linda, a physician assistant, share the busy practice with 3 other doctors, five medical assistants, and an Office Manager.

QUINTERO:
When I first heard about the registry, I went out to a local clinic to see it in action. After that, I really wanted to get our office involved. We were spending a lot of time doing paperwork for immunizations, especially hand transcribing, and I felt sure the registry could change that. And it does. It makes tracking immunizations so much easier and saves us time. It's very easy for all staff to use. And from my perspective as Office Manager, I've noticed that catching more missed opportunities is not only good for our patients, it's good for business.

DR. SCHWARTZ:
Carmen was the driving force behind getting us to use the registry. She really saw the potential, but it took the rest of us a little longer to see the light. Most pediatric practices would agree that if a child's record is incomplete, that patient risks either missing a dose, or even more likely, they may get a

duplicate shot, just because we can't verify the previous history. That's a waste of time for us and the parents and certainly no fun for the child. We can have a lot more confidence that this doesn't need to happen now because we can get a patient's full, up-to-date immunization history from the registry.

NEVERETT:
To say I was nervous about having to learn something new is an understatement. I didn't have that much experience with computers. I didn't want to change my old habits AND I thought this would take up too much of my time. I guess I can say I was pretty resistant at first. But I got a lot of help in the beginning. I really learn by doing so it was especially helpful to get hands-on training. And the system is pretty intuitive if you already know how to do manual charts. Eventually, I had to admit it was easier than doing it all by hand. Also, another big selling point for me was getting help with the vaccine inventories. I used to do those by hand and writing down all those lot numbers takes a lot of time. Now, I just enter the numbers once In the computer and there's no room for error. I also get a report on vaccine usage that gives me all the information I need to track our vaccine supply. Basically, I'm glad they talked me into it. It really does make my life easier.

QUINTERO:
Jill wasn't the only one dragging her heels. The initial struggle to get everyone on board was really about change. Change is the biggest obstacle in an office. Now it only takes new medical assistants about a week to get totally up to speed. I love to joke around with Carrie now because we both know she would never go back. We've become big supporters since using the registry and I've advised other practices in our county to join on. That will be happening soon.

SCHWARTZ:
Most private practices these days have to be really aware of expenses. So even allowing for the staff time to get up to speed, you need to have some buy-in that this will be useful. It may not show up immediately as savings to your bottom line, but it will make the office more efficient. Medical records, both paper and electronic, are getting a lot more scrutiny these days. It's reassuring to know the registry meets all the federal privacy and confidentiality requirements. Personally, I think systems like this are not only necessary and helpful--they're coming, ready or not. Getting involved early has always made sense to me. To some extent, using a registry takes a willingness to focus on longer-term benefits. But my office is proof that there's a big payoff-- not just with greater office efficiency--but actually improving the immunization rate for our practice. My take home message to other doctors is to get on board. For us to get the full benefit of a shared immunization database, all practices should be participating. Quite simply, the more of us that are involved, the more likely a child's record will be in the registry when we need it. That benefits all of us.

LINKINS:
These California practices point out some of the basic benefits of immunization registries. Registries put information into your hands. While state and regional systems may vary on details, most registries offer you a better idea of your own practice's coverage rates, monthly lists of your patients who are not up-to-date, data needed for HEDIS reports, tracking vaccine usage, and placing vaccine orders for VFC.

Immunization registries are an idea whose time has come. Registries are currently operational or under development in all 50 states and about half of these have state laws or administrative rules specifically authorizing registries. There are several states that now REQUIRE health care providers to report immunizations to a registry. But we still have our work cut out for us. Recent national data indicate that less than half of children under age six have at least two of their immunizations in a registry. This means there is still a huge gap to cover to meet the Healthy People 2010 objective of 95 percent of children with complete immunization histories. To achieve this goal, we need a paradigm shift. We must look at electronic immunization records and registries not as a dream for the future, but as a practice standard wherever immunizations are given to children. Programs around the country are committed to making the shift to a registry as painless as possible. But it will be up to health care providers, especially those of you in the private sector where the majority of immunizations are given, to get involved and to join up. If you'd like to learn more about immunization registries, including the contact person in your state, visit our registry website. The address is www.cdc.gov/nip/registry.

VACCINE BRIEFS

GOOD:
That clip was from a new video titled Safer Healthier Children: A Brief Introduction to Childhood Vaccines. The video is about 8minutes long and is intended to answer parents questions about immunizations. It's part of a public information package developed by the National Immunization Program.

The package is called the ABCs of Immunization. It includes not only the video, but also a series of PowerPoint presentations on immunization topics, such as how vaccines work, and vaccine safety.

The video and PowerPoint presentations are available on the National Immunization Program website. The video can also be ordered on tape. We will give you the address for the website at the end of the broadcast.

This segment of the program is Vaccine Briefs, short presentations on several topics of interest to vaccine providers. We will begin with hepatitis B vaccine. Donna?

HEPATITIS B VACCINE BIRTH DOSE

WEAVER:
Thanks, Cynthia. Our first vaccine brief concerns a change in the recommended infant hepatitis B vaccine schedule. Hepatitis B vaccine was added to the recommended childhood vaccination schedule in 1991. At that time, infants whose mothers were hepatitis B surface antigen positive, or whose surface antigen status was unknown, were recommended to receive the first dose of hepatitis B vaccine at birth. For all other infants, ACIP recommended that the first dose could be given at birth or as late as 2 months of age. No preferred age was specified.

In July 1999, the Public Health Service published a statement on the thimerosal content of childhood vaccines. The American Academy of Pediatrics published a similar statement in September 1999.

Unfortunately, these statements were misinterpreted by many providers. Some hospitals stopped giving birth doses completely, even in the absence of a good maternal screening program. The result of this was predictable: women infected with hepatitis B virus, or HBV, were missed, and infants were exposed to HBV at birth. Without a birth dose of hepatitis B vaccine, perinatal infections occurred. Many of the infections resulted in chronic infection in the infant. At least one infant death has been attributed to failure to administer a birth dose of hepatitis B vaccine.

The childhood vaccination schedule-including pediatric hepatitis B vaccine- is now essentially thimerosal free. But many physicians and birthing hospitals have been slow to resume the birth dose of hepatitis B vaccine.

To help remedy this situation, in October 2001, ACIP voted to recommend that all infants should receive the first dose of hepatitis B vaccine soon after birth and before hospital discharge. This recommendation was published in January 2002 in the childhood immunization schedule. The first dose may also be given as late as age 2 months, but ONLY if the infant's mother is documented to be hepatitis B surface antigen negative at the time of birth.

Prenatal testing of women for hepatitis B surface antigen is not fail- safe. Mistakes do occur and infection can also result from another source. The birth dose offers a safety net. AND there are other advantages to the birth dose. Data show that hepatitis B vaccine administration in the hospital increases the likelihood that all immunizations as well as the hepatitis B vaccine series will be completed on schedule. And finally, birth dosing provides an early opportunity to convey the importance of immunization to parents.

We hope that if you are not vaccinating with hepatitis B vaccine at birth that you will reconsider. AND, if you choose to use the hepatitis B- Hib combination vaccine, Comvax, you can still do so.

Only monovalent hepatitis B vaccine can be used for the birth dose. Comvax should NEVER be administered to children less than 6 weeks of age. Either monovalent or a combination vaccine containing hepatitis B may be used to complete the series for children 6 weeks of age and older. If you use Comvax, it can be given on a 2, 4, and 12 to 15 month schedule. The child will receive 4 doses of hepatitis B vaccine using this schedule, but this is not a problem.

Don't let infants fall through the cracks. Remember, they are the population most at risk for devastating consequences from hepatitis B virus infection. Protect and save lives by giving a birth dose of hepatitis B vaccine.

PNEUMOCOCCAL CONJUGATE VACCINE FAILURE

STRIKAS:
Our next vaccine brief concerns pneumococcal conjugate vaccine, or PCV. In February 2000, the Food and Drug Administration approved the first pneumococcal conjugate vaccine, a seven-valent vaccine with the brand name Prevnar. Shortly thereafter, the ACIP and the American Academy of Pediatrics recommended the use of PCV for all children 2 through 23 months of age, and children 24 through 59 months of age with increased risk for pneumococcal disease.

Since PCV was licensed for use, there have been reports of invasive pneumococcal disease among infants and children who had received at least one dose of the vaccine. But cases of invasive disease following vaccination are to be expected. In the clinical trials that led to licensure, vaccine efficacy was estimated to be 97 percent for invasive disease with pneumococcal serotypes included in the vaccine, and 89 percent for all serotypes. The reason that some vaccinated children appear not to be protected, particularly when the infection is caused by a serotype included in the vaccine, is not known.

It's important that we understand more about why some children fail to be protected following vaccination with PCV. We need your help to accomplish this. CDC's Respiratory Diseases Branch, in the National Center for Infectious Diseases, has developed a system to monitor and investigate this and other pneumococcal conjugate vaccine issues.

The system is intended to determine the serotype of these invasive pneumococcal isolates, determine conditions in the child that may increase the risk of severe pneumococcal disease, and monitor for vaccine lots that may be less effective. This tracking system is consistent with the Council for State and Territorial Epidemiologists recommendation that invasive pneumococcal disease in children less than 5 years old be placed under national surveillance.

There are four conditions that must be met in order for a case to be eligible for reporting. First, the child is less than 5 years old. Second, the child has an invasive pneumococcal infection. An invasive infection is defined as isolation of Streptococcus pneumoniae from a normally sterile site, such as cerebrospinal fluid, blood, joint fluid, or pericardial fluid. Third, there is a pneumococcal isolate available for serotyping. And, the fourth condition is the child has a history of at least one dose of PCV.

If all four conditions are met, a PCV failure case report form should be completed and sent along with the isolate and a CDC lab report form to your State Health Department. It's important to fill out the case report form as completely as possible, including the vaccination history.

Your State Health Department will send the isolate, case report form, and laboratory form to the Streptococcus laboratory at CDC. Cases of suspected PCV failure may also be reported to the Vaccine Adverse Events Reporting System, or VAERS. Reporting to VAERS about these cases is not required unless there is a clinically significant adverse event after vaccination with PCV.

The PCV Failure Case Report and an instruction sheet are available on the NIP website. The instruction sheet will provide information on how to complete the case report and send the isolate.

You will also find a link to the CSTE position statement on our website. We will include these websites on the resource page for this broadcast.

NATIONAL VACCINE SUPPLY

WEAVER:
Our next vaccine brief concerns the national vaccine supply. During the past two years, there have at various times been supply problems with six different vaccines, including influenza, adult Td, DTaP, pneumococcal conjugate, MMR, and

varicella. Health care providers and the public have been frustrated and worried by these shortages. But there is good news. With the exception of pneumococcal conjugate vaccine, the shortages have been resolved- for now.

For adult Td, MMR, DTaP, and varicella vaccines, supplies are sufficient to permit the resumption of the routine schedules. School and day care entry requirements should be reinstituted.

For Td and varicella, you should now recall persons whose doses were deferred. For DTaP and MMR, you should wait a month or two to recall those whose dose was deferred, because it will take a few months for supplies to be built up.

Unfortunately, demand for pneumococcal conjugate vaccine, or PCV, still exceeds the supply. Supplies are not expected to improve until the last quarter of 2002 or later. Because the duration of the shortage has been longer and the severity has been greater than anticipated, ACIP published revised recommendations in the MMWR on December 21, 2001. These recommendations are still in effect.

Until adequate supplies of PCV are available, ACIP recommends the following: health care providers should continue to vaccinate high-risk children 5 years of age or younger as originally recommended by the ACIP in October, 2000. This includes children with sickle cell disease and other hemoglobinopathies; anatomic asplenia; chronic diseases, such as chronic cardiac and pulmonary disease, and diabetes; cerebrospinal fluid leak; immunosuppression, including HIV infection, immunosuppressive chemotherapy or long-term systemic corticosteroid use; and children who have undergone solid organ transplantation.

Unvaccinated healthy children 6 weeks through 11 months of age should receive 2 doses of PCV separated by 1 to 2 months. The third and fourth doses should be deferred. Unvaccinated healthy children 12 to 23 months of age should receive one dose. Unvaccinated healthy children 24 months of age and older should not be vaccinated at this time.

As with any deferral due to vaccine supply, health-care providers should maintain a list of children for whom PCV has been deferred. These children should be recalled and vaccinated as age-appropriate when supplies are adequate. During recall, highest priority should be given to infants who received only 2 doses. Infants who received 3 doses and are eligible for a fourth dose would be a second priority group. Pneumococcal polysaccharide vaccine is not licensed or recommended for children less than 2 years of age. Do NOT substitute pneumococcal polysaccharide vaccine for PCV in children less than 2 years of age.

The table for vaccinating healthy children with PCV during a moderate or severe shortage is included in the MMWR article published December 21, 2001. The article, which is available on the NIP website, also includes some limited efficacy data and the rationale for these revised recommendations. CDC will continue to monitor vaccine supply and post updates about vaccine supply and shortages on the NIP website. All of these resources will also be posted on the resource web page for this broadcast.

DAPTACEL DTaP VACCINE

STRIKAS:

On May 14 of this year, the Food and Drug Administration approved a new diphtheria, tetanus, and acellular pertussis vaccine.

This new DTaP vaccine is called DAPTACEL and it's manufactured by Aventis Pasteur. DAPTACEL is licensed for the first 4 doses of the DTP series in infants and children 6 weeks through 6 years of age. The vaccine is a little different than other DTAP vaccines licensed in the United States in that it contains 4 pertussis components. Tripedia and Infanrix contain 2 and 3 components, respectively. The efficacy and safety profile is similar to that of other DTAP vaccines.

DAPTACEL has been approved for administration as a 4 dose series at 2, 4, 6 and 17-20 months of age. However, we recommend that you apply the same age and interval rules to DAPTACEL that ACIP recommends for other DTAP vaccines.

Specifically, the recommended schedule is 2, 4, 6 and 15 to 18 months of age with the fifth and final dose at 4 to 6 years of age. The minimum age for starting the DTAP series is 6 weeks.

There is a minimum interval of 4 weeks between the first 3 doses, and a minimum interval of 6 calendar months between the third and fourth doses. Although ACIP recommends that the fourth dose be given at 15 to 18 months of age, it may be given as early as 12 months of age if the child is unlikely to return for an additional visit at 15 to 18 months of age, and at least 6 months have elapsed since the third dose.

There are limited data on the safety, immunogenicity, or efficacy of interchanging DTaP vaccines during the primary series or for booster doses. ACIP recommends that whenever feasible, the same DTAP vaccine should be used for the entire vaccination series. However, if you do not know or do not have available the type of DTAP vaccine the child received previously, DON'T MISS THE OPPORTUNITY TO VACCINATE. Use any of the 3 licensed DTaP vaccines to complete the vaccination series.

GLOBAL POLIO ERADICATION

WEAVER:
For our last vaccine brief, we would like to update you on the status of global polio eradication. The Global Polio Eradication Initiative was launched by the World Health Assembly in 1988. It's coordinated by the World Health Organization in partnership with the CDC, Rotary International, and UNICEF. National governments, private foundations, nongovernmental organizations, corporations, and volunteers are all collaborating to achieve eradication.

In 2000, about 29 hundred confirmed polio cases were reported from 20 countries. During 2001, a total of only 494 confirmed cases of polio were reported from 10 countries.

These 10 countries, shown on this map in red are located in 3 WHO regions- Africa, Eastern Mediterranean, and South East Asia. The largest number of cases was reported from Pakistan and India.

Another major milestone was achieved in June 2002, when the European region was certified as free of indigenous wild poliovirus transmission. The European

region includes 51 countries, from western Europe through the countries of the former Soviet Union, and has a population of 870 million. The European region is the third WHO region to be certified free of indigenous wild virus polio. This follows certification of the Region of the Americas in 1994, and the Western Pacific Region in 2000. An estimated 3.4 billion people, or 55 percent of the world's population, now live in countries and territories certified free of endemic wild poliovirus transmission.

Several challenges to global eradication remain. Among them: maintaining high-quality surveillance and immunization activities; gaining access to children in conflict affected countries; providing sufficient oral polio vaccines; and ensuring political and financial support until certification of global eradication is achieved in 2005.

YOU may be able to help meet at least one of these challenges. CDC continues to recruit health care professionals for short-term field assignments to polio endemic countries. This program is called Stop Transmission of Polio, or STOP.

Here is Dr. Linda Quick, coordinator of the STOP program, to tell you about it.

QUICK:
The global program for polio eradication began in 1988, and is led by the World Health Organization. WHO has many partners in this effort, including UNICEF, Rotary International, the Centers for Disease Control and Prevention, and the Ministries of Health of every country in the world.

Over the years, CDC has provided technical expertise, especially in epidemiology, surveillance and laboratory science, not only to the WHO and UNICEF, but also to individual countries. During the smallpox eradication program CDC played a vital role along with WHO in providing technical support to many countries for surveillance and containment strategies. The Stop Transmission of Polio or STOP teams provide the same type of technical support for the polio eradication program.

The global polio eradication initiative is now in its final phase. But the challenges that remain are the most difficult ones. The few remaining countries with wild poliovirus transmission must increase immunization coverage rates, add special polio immunization days and improve their polio surveillance in the midst of many competing public health priorities. In order to help these countries eradicate poliovirus, we initiated the STOP team program. The objective of the STOP program is to accelerate the progress of the polio eradication program. This is accomplished by assigning volunteer consultants to polio endemic countries for three-month tours of duty.

In 1999 the first group of 25 STOP team members were assigned to 5 countries: Bangladesh, Yemen, Burkina Faso, Nepal and Nigeria. Since that time, eight STOP teams, comprising 286 health professionals, have been assigned to 22 different countries. STOP team volunteers have been U.S. citizens, as well as volunteers from 23 other countries.

So, what do STOP team members really do? There are 2 activities, or terms of reference for the STOP teams. The specific activities depend on the needs of the country to which the person is assigned. The most frequent activity is to assist national staff by troubleshooting and improving the flaccid paralysis

surveillance system. This requires a lot of travel to various reporting units, such as clinics and hospitals. Some reporting sites may be in very remote locations. Once at the reporting location, the consultant will help determine the quality of their surveillance and the understanding of the health care workers of the surveillance system. Consultants frequently provide training to health facility staff. There are also opportunities to assist in case investigation of children with paralysis. Last year, there were thousands of paralytic cases reported, all of which needed to be investigated.

The second term of reference is to assist national staff with polio immunization days. During a national immunization day, all children under 5 years of age receive oral polio vaccine on the same day. NID activities may include mapping and other preparatory functions, helping to ensure that the logistics of transporting vaccine are in order, transportation of vaccinators are intact and working side by side with the national staff monitoring house to house vaccination campaigns.

So who makes up the STOP teams? And what qualifications are we looking for? STOP team members come from diverse backgrounds. There are CDCc staff, non-CDC professionals, as well as qualified international volunteers. The common link between all STOP team members is an appreciation and understanding of public health, surveillance and epidemiology. This mission can be quite difficult. Team members are assigned to polio endemic countries, often the poorest countries in the world. Once there, team members will travel to the highest risk areas to conduct surveillance, investigate cases and participate in vaccination activities.

As important as the technical qualifications is the ability to work well with others of a different culture. This quality is imperative to the success of a mission. This requires not only strong professional expertise but also the ability to work comfortably outside of one's own culture. Team members are expected to live at the district level, which may lack medical facilities, healthy food or comfortable accommodations.

A STOP team assignment isn't for everyone. But it can be a very rewarding experience. If you are interested and would like additional information please contact us. This could be your opportunity to participate in one of the greatest achievements of medical history, the eradication of polio virus from the earth.

[UNSCRIPTED VIDEO PROMO]

GOOD:
That clip was from a video on vaccine administration produced by the California Immunization Program. It's called Immunization Techniques - Safe, Effective, Caring. The video is 35 minutes long and covers all aspects of vaccine administration, including reconstitution and drawing vaccine, anatomic sites, needle length, administration techniques, and more.

The video and associated material costs 25 dollars and is available from the California Distance Learning Health Network. You can order the tape from the CDLHN website at www.cdlhn.com. You can also call them to order the tape. The number is 619-594- 3348. The video includes presenter's notes, a skills checklist, immunization site maps, and other materials. The video and related materials are now also available in Spanish, which may be helpful for your

bilingual staff. The video and other materials will be a great competency- based training tool for your office.

GOOD:
This brings us to the end of this edition of Immunization Update. Before we go, we would like to give you a few additional resources you can use to get more information about the topics we covered in today's program. We have created a special page on the National Immunization Program website to provide one stop shopping for many of the documents and materials we have discussed today. There are also links to information on other vaccine related topics and resources. The address is www dot cdc dot gov slash nip. Click on the Health Care Professional tab.

If you have questions that we didn't answer on the air, or wish to order materials and don't have Internet access you can call the National Immunization Information Hotline at 800-232-2522. The Hotline is staffed Monday through Friday from 8 AM until 11 PM eastern time.

You can use the Internet to E-mail questions, comments, or requests directly to the National Immunization Program. The address is nipinfo@cdc.gov. That Email address again: is nipinfo@cdc.gov.

Finally, if you would like to find out more about upcoming Public Health Training Network courses, visit the PHTN website at www dot phppo dot cdc dot gov slash phtn.

GOOD:
Thank you for joining us for this edition of Immunization Update. We've enjoyed bringing it to you. Goodbye.

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